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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/658,034	09/09/2003	Jean-Pascal Zambaux	ATMI-658	2051
25559	7590	06/08/2006	EXAMINER	
ATMI, INC. 7 COMMERCE DRIVE DANBURY, CT 06810			MIGGINS, MICHAEL C	
		ART UNIT		PAPER NUMBER
		1772		

DATE MAILED: 06/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	10/658,034	ZAMBAUX, JEAN-PASCAL
	<b>Examiner</b> Michael C. Miggins	<b>Art Unit</b> 1772

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 07 March 2006.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 14,15,17-19,23-26 and 28-38 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 14-15, 17-19, 23-26, 28-38 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                     | Paper No(s)/Mail Date. _____ .  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____ .                                  |

**DETAILED ACTION**

**REJECTIONS WITHDRAWN**

1. All of the 102 and 103 rejections either repeated or set forth in the non-final rejection of 12/7/05, pages 2-6, paragraphs 3-7 are withdrawn.

**REJECTIONS REPEATED**

2. There are no rejections repeated.

**NEW REJECTIONS**

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 14-15, 17-19 and 29-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yokokoji et al. (US 4212299) in view of Herbert (US 4561110).

Claims 32-33 recite method limitations (the terms "welding" and "ultrasonic") in a product claim, the method limitations have been given little patentable weight since the method limitations do not further structurally limit the product claim and because method limitations are not germane to the patentability of a product claim (MPEP 2113).

Claims 14 and 23 recite the method steps of heating the bag to approximately 253 degrees C for approximately 30 minutes in a product claim, the method limitations

have been given little patentable weight since the method limitations do not further structurally limit the product claim and because method limitations are not germane to the patentability of a product claim (MPEP 2113). However, Herbert discloses the step of sterilization via heat at any temperature of 120 degrees C or more (column 7, lines 56-65).

Yokokoji discloses an apparatus comprising a bag, which contains blood (abstract and column 1, lines 5-20, column 3, lines 15-63), comprised of a polymeric film comprising PTFE, or PFA, or ECTFE (column 3, line 15 through column 4, line 34), and a second layer which is coupled to the first film containing one of the materials possible for the first layer (column 4, lines 5-34) and a connector (column 4, lines 29-34) wherein the thickness of each layer is from 15 to 50 microns (column 4, lines 44-47) (applies to instant claims 14-15, 17-19 and 29-31).

Yokokoji does not specifically disclose a pyrogen free bag.

Herbert specifically discloses a bag which is pyrogen free (column 8, lines 1-26) that contains blood (abstract) for the purpose of providing a sterilized bag free of pyrogens.

Therefore it would have been obvious to one of ordinary skill in the art at the time applicant's invention was made to have provided a bag which is pyrogen free in the invention of Yokokoji in order to provide a sterilized bag free of pyrogens as taught or suggested by Herbert.

Herbert discloses two sheets sealed at the edges (Fig. 6) (applies to instant claims 31-33).

5. Claims 23-26 and 34-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yokokoji et al. (US 4212299) and Herbert (US 4561110), as applied to claims 14-15, 17-19 and 29-33 above, and further in view of Leunberger (US 5314421).

Claims 36-38 recite method limitations (welding and sealing steps) in a product claim, the method limitations have been given little patentable weight since the method limitations do not further structurally limit the product claim and because method limitations are not germane to the patentability of a product claim (MPEP 2113).

Yokokoji discloses an apparatus comprising a pyrogen free sterilized bag, which contains blood (abstract and column 1, lines 5-20, column 3, lines 15-63), comprised of a polymeric film comprising PTFE, or PFA, or ECTFE (column 3, line 15 through column 4, line 34), and a second layer which is coupled to the first film containing one of the materials possible for the first layer (column 4, lines 5-34) and a connector (column 4, lines 29-34) wherein the thickness of each layer is from 15 to 50 microns (column 4, lines 44-47) (applies to instant claims 23-26, 34-36).

The limitation wherein the bag is suitable for heating to at least approximately 253 degrees C for at least approximately 30 or 60 minutes is necessarily present in the invention of Yokokoji since the reference discloses the same materials as applicant (column 3, lines 15-63) and since all the materials have thermal resistances above 200 degrees C (column 5, lines 5-15). Furthermore, it would have been obvious to one of ordinary skill in the art at the time applicant's invention was made to have provided such

heat resistance in order to prevent the bag from degrading during sterilization (applies to instant claims 23 and 28).

The difference between the instant claims and Yokokoji is that Yokokoji fails to disclose instructions or indicia located on the packaging material or inside the packaging material.

Leuenberger discloses instructions or indicia located on the packaging material or inside the packaging material (abstract, column 4, lines 1-45) in a blood pack (column 3, lines 43-50) for the purpose of providing storage information (column 1, lines 5-20) (applies to instant claim 23).

Therefore it would have been obvious to one of ordinary skill in the art at the time applicant's invention was made to have provided instructions or indicia located on the packaging material or inside the packaging material on the bag of Yokokoji in order to provide storage information as taught or suggested by Leunberger.

#### **ANSWERS TO APPLICANT'S ARGUMENTS**

6. Applicant's arguments filed 3/7/06 have been considered but are moot in view of the grounds for rejection set forth above.

#### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Miggins whose telephone number is 571-272-1494. The examiner can normally be reached on 1:00-10:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Y. Pyon can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Michael C. Miggins  
Primary Examiner  
Art Unit 1772

MCM  
May 30, 2006.

